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D3

8. The vaccine according to claim 6 wherein said ciliated protozoans are taxonomically related to *Ichthyophthirius multifiliis*.

#### REMARKS

Reconsideration of the patentability of the claims of the above identified patent application is solicited in view of the above amendments and the following comments.

It is believed that the Petition for extension of time that has been filed is sufficient to maintain the pendency of this application and that no further petition for extension of time is required in this matter. However, if one is required, kindly consider this to be such a petition for however long is required to maintain the pendency of this application. It is believed that the fee that has been paid with the filing of this paper is correct. However, if any additional fee is due, kindly charge the same to the undersigned attorneys' deposit account 07-1337.

There is being filed herewith a partially executed original of a declaration under the provisions of 35 USC 131 attesting to the fact that the cited He et al. article has an effective publication date that is less than one (1) year prior to the effective filing date of this application, and that whatever subject matter that publication may have in common with the instant claimed subject matter is attributable to the instant named inventors. Therefore, since the reference is not available under 35 USC 102(b), and it is a publication that is effectively by the inventors of the instant claimed invention, it is not a valid reference against the patentability of the instant claims. A further

original of this declaration is in the hands of several of the other authors of the referenced publication and will be filed as soon as it is completely executed.

A certified copy of the priority Singapore application has been requested from the Singapore Patent Office. It will be filed as soon as it is received.

The examiner has objected to claim 3 as not being supported by the specification. That position of the examiner is respectfully traversed. The objected to language is “substantially inert medium”. The examiner complains that there is no basis in the specification for that term. It should be clear to any chemist that, to be an effective medium, the material that constitutes the medium should be substantially inert to the recombinant fusion product admixed therewith. It is therefore inherent in the instant invention that the medium should be substantially inert. That the medium should be “substantially” inert merely states the obvious. Inserting this obvious (to any organic chemist) fact into the claims does not constitute prohibited new matter.

In chemistry, there is no absolute inertness that can be measured at the molecular level. Thus the term “**substantially** inert” is entirely appropriate from a pragmatic and practical perspective. Most importantly, claim 3 is an original claim and is therefore self supporting. If the examiner wishes, applicants are prepared to amend the instant specification to incorporate the subject matter of originally filed claim 3 therein.

However, in order to expedite the prosecution of this application, the term, “substantially inert” has been removed from claim 3. It is not believed that the deletion of this term from this

claim introduces any prosecution history estoppel as this deletion actually broadens the claim. There has been no “giving up” of claim scope in order to support patentability. Rather, the examiner has insisted that the claim scope be enlarged, which the applicants have reluctantly complied with. In any case, withdrawal of this objection is solicited.

In the outstanding action, the examiner has objected to claim 5 because of a minor typographical error. The above amendment has corrected this error. This correction of a minor typographical error does not constitute the introduction of prohibited new matter. This amendment too does not raise any prosecution history estoppel as it does nothing to the substance of the claim. The change is editorial in nature only and therefore cannot be construed as raising any sort of estoppel directed to patentability of the claim.

In the outstanding action, the examiner has objected to claims 7 and 8 for their recitation of “ciliated protozoan”. Claim 7 is dependent from claim 6. That parent claim provides antecedent basis for the use of this term in claim 7. Claim 7 is an original claim and is therefore self supporting. Therefore the objection to claim 7 should be withdrawn. Claim 8 has been amended to also depend from claim 6. Claim 6 well provides antecedent basis for this term in claim 8. It is therefore urged that this objection be withdrawn.

In paragraph 12, the patentability of claims 1-7 has been rejected on the basis of anticipation by the disclosure of the cited He et al. publication. As noted above, this is effectively a publication of the inventors that does not comply with 35 USC 102(b). Therefore, insofar as this reference discloses subject matter that is in the instant claims as well, it is not a valid prior art reference

because it is a publication of the inventors. A declaration supporting this position is being filed herewith. This rejection must therefore be withdrawn.

In paragraph 13, claims 1 and 8 have been rejected as being directed to subject matter that allegedly would have been obvious to a person of ordinary skill in the art at the time that the invention was made in view of the combined disclosures of the cited He et al. and Clark et al. references. The He et al. publication is not available as a reference for the reasons set forth above. The Clark et al reference does not support a rejection of the patentability of the instant claims absent the He et al. primary reference. Therefore this rejection must be withdrawn as well.

Insofar as the objection raised in paragraph 15 of the outstanding office action is concerned, it is readily apparent that the examiner has indeed considered the pertinence of the references supplied by the applicants. Note that the citation of references by the examiner is a copy of the 1449 form submitted by the applicants. Note also that the examiner has placed his initials next to the most pertinent of the references that were cited by the applicant. It is suggested that, in order for the examiner to have done so, he must have obtained copies of these references and considered them. There is no apparent reason why the examiner singled out only the references that were initialed for consideration without considering the other references as well. In any case, it is clear that the examiner was not in any way discomforted by the form of applicants' IDS and cited references. Should the examiner wish to be provided with any of the other references cited by the applicants, contact with the undersigned attorney will bring those copies in short order.

The specification has been objected to as containing prohibited new matter. The examiner has objected to the references to the drawing that was submitted after the application was filed. This position of the examiner is categorically traversed. The original text of the application, including reference to the short description of the drawing and the several references to the drawing by reference number cannot be prohibited new matter as it was original content of the application as filed. The drawing is merely a pictorial representation of the subject matter that is fully described in the specification. As such it does not constitute prohibited new matter. The specification is replete with written descriptive matter that supports the drawing. The drawing and the written specification, as originally filed, describe exactly the same invention. The invention that was described in the originally filed application is what is being claimed in the originally filed (and presently amended) claims of this application. The drawing merely presents the same information that was described in the originally filed specification in a different format. The instant claims are entirely supported by the application as originally filed and would be entitled to the same filing date regardless if the drawing was there or not. Therefore, the submitted drawing does not constitute prohibited new matter.

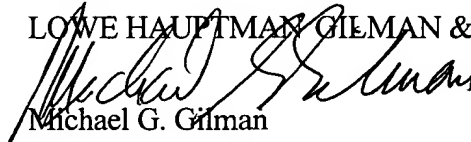
It is pointed out that this is a chemical, rather than a mechanical, invention. Chemical inventions do not require a drawing for effective support under 35 USC 112. The matter displayed in the drawing is inherently the same, albeit in a different form, as what is disclosed in narrative form in the original specification. It is urged that the examiner withdraw his objection to the inclusion of the drawing.

Objection has been raised to the inclusion of SEQ. ID NO 19. It is pointed out that the extent and the numbering of the sequences in this application are the direct result of instructions given to the undersigned attorney by the prior examiner (Ms. Lee). A review of the record will indicate this. Further, the SEQ. ID Nos. have been assigned by the program PATENTIN, which the PTO has required applicants to use. Applicants cannot now be faulted for complying with the examiner's insistence and for including something that the PTO's required program created. However, if it will expedite the prosecution of this application, applicants are prepared to resubmit the sequence listings for this application in PATENTIN 3.0. It is possible that doing so may obviate the objections raised by the examiner. If the examiner wishes this, kindly contact the undersigned attorney. The information requested by the examiner is not presently available and even if it was, its submission would not change this application in any material respect. The examiner is urged to advise the undersigned attorney of how he wishes this matter to be resolved.

In view of the above comments and amendments, it is believed that the instant application is now in condition for allowance and such action is solicited.

Respectfully Submitted,

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ATTACH: Copy of a partially executed Declaration under 37 CFR 1.131

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## APPENDIX

### CLAIM AMENDMENTS

3. The vaccine according to claim 1 further comprising a [substantially inert] medium comprising at least one of buffers, adjuvants, immunostimulants or carriers.

5. The vaccine according to claim 2, wherein the fusion protein[.] is produced using E-coli.

8. The vaccine according to claim [1] 6 wherein said ciliated protozoans are taxonomically related to *Ichthyophthirius multifiliis*.